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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/938,670 | 08/27/2001 | Jens Petersen | 60117.000007 | 2509 |

7590

01/29/2004

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/29/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,670

Applicant(s)

PETERSEN, ET AL

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-40 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) 13-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7-12 and 44-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other:

Status of the Claims

Claims 13-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 3,4,6 have been cancelled. Claims 44-47 are newly added.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12,44,46,47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite. It is not clear what the claimed limitation intends for the use of the gel. Is the gel used as an implantable prosthesis? Is the gel used in combination with an implantable prosthesis? Moreover, the metes and bounds of the recitation of "suitable for" fails to positively set forth the physical characteristics that make the gel "suitable" for an implantable endoprosthesis.

Claim 44, see rejection to claim 12 supra.

Claim 46, is indefinite. The preamble of the claim is directed to the hydrogel and the body of the claim intends to claim the combination of the hydrogel and a silicone envelope.

Claim 47, see rejection to claim 46 supra. The composition ie. hydrogel, as set forth in the preamble does not include the general use of the hydrogel as a therapeutic carrier, implant, endoprosthesis, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,5,7,8,9,10,11,12,44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait (5658329) in view of Topalov, et al (WO 99/10021) and Lopatine (WO 01/49336).

According to the disclosure of Purkait, the hydrogel contains between 2-20% by weight of polyacrylamide in pyrogen-free water. The claim fails to disclose the cross-linking agent of methylene bis-acrylamide in forming the polyacrylamide. Topalov, et al and Lopatine teaches using methylene bis-acrylamide in forming polyacrylamide. If not inherent in Purkait, to use methylene bis-acrylamide in forming the polyacrylamide of Purkait would have been obvious to one with ordinary skill in the art based on selection of one well know cross-linking agent used in radical initiation of an acrylamide. Note, Lopatine teaches that the ppm of the acrylamide is less than 50 ppm. The viscosity range of the hydrogel as disclosed by Purkait is within the range as claimed by applicant. Since the viscosity and the molar ratio of the acrylamide and the methylene

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bis-acrylamide fall within the molar ratio and viscosity as claimed examiner contends that the modulus of the material would inherently fall within the modulus as claimed by applicant.

Clearly the hydrogel of Purkait could be used in an injectable form as required for claim 44 and as well as it's use in combination with a silicone envelope as taught by Purkait.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait as modified by the secondary references as applied to claim 1 above, and further in view of Breitbart (5700289).

The use of hydrogel as a carrier for cells in surgical treatment for tissue repairs is known to old as taught by Breitbart, et al. To use the hydrogel of Purkait as a carrier for specific cells to assist in repair of damaged or removed tissues would have been obvious to one with ordinary skill in the art from the teachings of Breitbart.

Conclusion

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

dji
January 26, 2004